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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/576,631 | 04/16/2007 | Stephen O'Hara | CARP-001/00US<br>307428-2001 | 5768 |

58249 7590 05/23/2008

COOLEY GODWARD KRONISH LLP
ATTN: Patent Group
Suite 1100
777 - 6th Street, NW
WASHINGTON, DC 20001

| EXAMINER | |
|---|---|
| OGUNBIYI, OLUWATOSIN A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/23/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/576,631 | O'HARA, STEPHEN | |
| | Examiner | Art Unit | |
| | OLUWATOSIN OGUNBIYI | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☒ Claim(s) *4 -15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-15 are pending in the application and are under examination.

### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Claim Objections*

Claims 4-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not serve as a basis for any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Zolopa et al. (Ann Intern Med 1999; 131:813-821).

The claims are drawn to a process for analyzing a biological sample, comprising the steps of: (a) identifying a micro-organism present within the sample; and (b) determining the effect of one or more antimicrobial(s) on a micro-organism from the sample, wherein steps (a) and (b) are performed by analyzing the micro-organism's nucleic acid.

Zolopa et al teach a process for analyzing plasma samples from HIV patients comprising the steps of

(a) identifying the HIV virus genotype from the sample (by performing polymerase chain reaction (PCR)/nucleic acid amplification on said sample to identify HIV virus in the plasma samples (p. 814 column 2 under HIV genotyping) thus analyzing the virus's nucleic acid and

(b) determining the effect of antiretrovirals on HIV RNA levels by analyzing the nucleic acid (RNA) of said HIV virus by using nucleic acid amplification e.g. PCR followed by a sequencing of the PCR product (a nucleic acid hybridization assay) (p. 814 second column under HIV genotyping, p. 815 under virologic outcomes and figure 1).

The PCR of both a and b above is also a nucleic acid hybridization assay because PCR is an assay that involves the hybridization of nucleic acid (primers) to another nucleic acid target.

2. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kain et al. ( Am. J. Trop. Med. Hyg., 49: 478-484, 1993).

The subject matter of the claims is set forth supra.

Kain et al teach a process for analyzing filter paper blood samples from patients comprising the steps of

(a) Identifying the presence of Plasmodium vivax species within the filter blood sample by polymerase chain reaction (PCR) thus analyzing the nucleic acid of the Plasmodium

(b) and determining the effect of chloroquine on said Plasmodium by analyzing the nucleic acid of said Plasmodium (see abstract and under materials and methods) – patients were treated with chloroquine and then their blood samples were analyzed for Plasmodium vivax for a portion of the circumsporozoite gene (CS) by PCR and genotyped by oligoprobes (nucleic acid hybridization assay – the mean time to clear parasitemia due to chloroquine treatment in said patients was determined using said PCR/oligoprobe assay (see abstract p. 478 and see under subjects, materials and methods on p. 479).

The PCR of both a and b above is also a nucleic acid hybridization assay because PCR is an assay that involves the hybridization of nucleic acid (primers) to another nucleic acid target.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Troesch et al. ( Journal of Clinical Microbiology, Jan. 1999, p. 49-55).

The subject matter of the claims is set forth supra.

Troesch et al teach a process for analyzing Mycobacterium clinical isolates (obtained from clinical samples/specimens, p. 49 column 2 under bacterial strains, phenotypic identification and susceptibility testing) comprising the steps of

(a) Identifying the Mycobacterium species obtained from clinical samples by analyzing the nucleic acid of said Mycobacteria (p. 50 column 2 under identification of Mycobacterium species)

(b) and determining the effect of rifampicin on said Mycobacteria by analyzing the nucleic acid (the *rpoB* sequence) of said Mycobacteria (p. 51 column 2 under Detection of *M. tuberculosis* rpoB mutants and p. 50 column 1 first incomplete paragraph).

Identification of said Mycobacterium species involves a nucleic acid hybridization assay (table 1 and table 1 figure legend) and determining the effect of rifampicin on said Mycobacteria by analyzing the nucleic acid of said Mycobacteria involved a nucleic acid hybridization assay (see p. 51 fig. 1 and column 2) and both processes (a and b) involved the amplification i.e. polymerase chain reaction of nucleic acid from said Mycobacteria p. 50 column 1 under target preparation and p.51 fig. 1). The PCR of both a and b above is also a nucleic acid hybridization assay because PCR is an assay that involves the hybridization of nucleic acid (primers) to another nucleic acid target.

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Rustad et al. (Microbiology 148:1061-1072, 2002).

Rustad et al teach a process for analyzing *Candida* clinical isolates (obtained from clinical samples, p. 1062 column 1 under strains and growth of cultures) comprising the steps of (a) identifying the type of Candida genotype obtained from clinical samples by analyzing the Candida nucleic acid by PCR (fig.2) or nucleic acid hybridization

(b) and determining the effect of antifungal on Candida by analyzing the nucleic acid of said Candida (i.e. the genotype) using nucleic acid amplification e.g. PCR and a nucleic acid hybridization assay (Southern Blot) (1064 under results to page 1065 column 1 first incomplete paragraph and table 3) and correlating with antifungal (fluconazole resistance) ( p. 1064 table 2, p. 1065 table 3, p. 1066 fig. 4). The PCR of both a and b above is also a nucleic acid hybridization assay because PCR is an assay that involves the hybridization of nucleic acid (primers) to another nucleic acid target.

***Status of the Claims***

Claims 1-3 are rejected. Claims 4-15 are objected to as being improper multiple dependent claims (see under objection supra). No claims allowed.

***Prior Art Made of Record Pertinent to the Instant Disclosure***

1. Pfaller et al. The Clinical Microbiology Laboratory and Infection Control: Emerging Pathogens, Antimicrobial Resistance and New Technology. Clinical Infectious Diseases 1997;25:858-70 – teaches various genotypic typing for microorganisms.

2. Anthony et al. Rapid Diagnosis of Bacteremia by Universal Amplification of 23S Ribosomal DNA followed by Hybridization to an Oligonucleotide Array, Journal of Clinical Microbiology Feb. 2000, p. 781-788

3. Brennan et al. Evaluation of Coxiella burnetti Antibiotic Susceptibilities by Real-Time PCR Assay. Journal of Clinical Microbiology May 2003, p. 1869-1874.

4. Mahbubani et al. Applications of Polymerase Chain Reaction Methodology in Clinical Diagnosis: In PCR Technology Current Innovations Chapter 31 p. 307-326.

5. Anthony et al. DNA Array Technology and Diagnostic Microbiology. Expert Rev. Mol. Diagn 1(1), 30-38 (2001) - teaches PCR and nucleic hybridization for genotyping or determining drug resistance by microorganisms.

6. Tenover et al. Antimicrobial Susceptibility testing In: Clinics in Laboratory Medicine, WB Saunders, Philadelphia, PA. 1989 June; 9(2): 341-7

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Examiner Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Oluwatosin Ogunbiyi/

Examiner, Art Unit 1645

/Patricia A. Duffy/

Primary Examiner, Art Unit 1645